

consisting of polypropoxylated cetyl alcohol and ethoxylated cetyl alcohol.

Remarks

Claims 1, 4, 15, 21-23, and 31 have been cancelled. Claims 3, 5, 9, 11, 12, 17, and 28 have been amended. New claims 32 and 33 have been added. Claims 3, 5, 9, 11-13, 17, 28, 32, and 33 are now in the application. Reconsideration and allowance of these claims as now presented is respectfully requested.

Rejection of Claims Under 35 U.S.C. §112

Claims 1, 3-5, 9, 11-12, 17, 23, and 28 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims as now amended do not include the phrase that was objected to under §112 in the Official Action dated March 24, 2004. Withdrawal of the claim rejections under 35 U.S.C. §112 is therefore warranted.

Rejection of Claims Under 35 U.S.C. §103

Claims 1, 3-5, 11, 17, 23, and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. (GB 2,202,145) in view of Jacobs et al. (U.S. 5,939,085) and Sang et al. (U.S. 6,143,310). Totten et al. '145 generally disclose dermatological compositions having nedocromil sodium and ethoxylated mixtures of cetyl and

stearyl alcohols. The Jacobs et al. '085 patent is generally directed to skin smoothing compositions, including surfactants such as disodium cocoamphodiacetate. Sang et al. '310 disclose a cosmetic composition, and identify PPG-5 ceteth-20 as a suitable solubilizing agent.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to add the disodium cocoamphodiacetate of Jacobs et al. '085 to the composition of Totten et al. '145. The Examiner states that the incentive to combine the components of these references lies in the fact that surfactants are known to increase the stability of emulsions. While Applicant agrees that certain surfactants are known to increase the ability of emulsions, there is no suggestion in Totten et al. '145 that an increase in emulsion stability is needed or desired. Therefore, it would not have been obvious to one of ordinary skill in the art to add an amphoteric surfactant to the composition of Totten et al. wherein no added stability is needed or desired.

In addition to the above, the cited references, whether taken alone or in combination, fail to teach or suggest the unexpected results of the present invention,

particularly that of an effective topical treatment for skin maladies.

It is well established law that even in the event that the prior art describes a composition, that composition is not obvious in view of prior art if the claimed properties of the composition are not obvious (see Ortho Pharmaceutical v. Smith, 15 U.S.P.Q. 2d 1856, 1862 (E.D.Pa 1990). The seminal case in this aspect of law is In re Papesch, 315 F.2d 381, 391 (CCPA 1963), wherein the court stated that "a compound and all of its properties are inseparable and must be considered in the determination of obviousness". Accordingly, it is well settled that unexpected properties of a known composition are non-obvious and patentable.

In Applicant's response filed September 29, 2003, a Declaration of Alan Edwards was submitted demonstrating the unexpected results of the claimed compositions in direct comparison to the compositions of Totten et al. '145. This direct comparison is brought about by demonstrating in detail the positive results observed when the compositions of the present invention are topically applied for the treatment of skin conditions, as contrasted with the express statement in the Van Bever article that analogous compositions of the prior art, and specifically that of

Totten et al., "have no advantage over placebo". Accordingly, the Declaration submitted on September 29, 2003 in fact directly compares the effectiveness of the compositions of the present invention to that of Totten et al. '145.

The Examiner asserts that the tables of Exhibit A in the Declaration of Alan Edwards fail to provide results of statistical significance. Applicant, however, strongly submits that the supplied evidence demonstrating an effectiveness is indeed a result of statistical significance, as compared to no effectiveness that is the clearly established result of Totten et al. '145. Health ailments, such as those treated in the compositions of the present invention, are either treated or not treated by medications. The results previously submitted clearly demonstrate that the compositions of the invention treat patients' ailments, while medications of the prior art did not treat such ailments. Applicant again submits that this stark distinction is truly significant, both in terms of patent law, as well as to the well-being of afflicted patients. The demonstrated differences in effectiveness of the compositions of the present invention, as compared to those of Totten et al. '145, directly address the issue of unexpected results.

The court in In re Hoch, 428 F.2d 1341, 1345 n.5 (CCPA 1970) stated that unexpected results include "differences in degree of the same property amounting to marked superiority". Here, treatment of patients having skin conditions, which treatment results in some improvement is indeed a marked superiority over treatments that results in no improvement. Accordingly, Applicant respectfully submits that the submissions made on September 29, 2003 clearly demonstrate results which are unexpected in view of the cited prior art.

The claims have been amended as suggested by the Examiner to recite a method of treating a skin condition in accordance with the experimental results demonstrated in this case.

For the foregoing reasons, Claims 3, 5, 11, 17, 28, as well as all other pending claims are believed to be unobvious and patentable over the cited prior art, and particularly over Totten et al. '145 in view of Jacobs et al. '085 and Sang et al. '310. The claim rejections based thereon should accordingly be withdrawn.

Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085 and Sang et al. '310 and further in view of Dener et al. (WO 98/04537) and Haider (1979). The

references of Dener et al. '537 and Haider, whether taken alone or in combination, fail to cure the defects of the cited references discussed above. Therefore, the claim rejections based thereon should be withdrawn.

Claim 12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085 and Sang et al. '310, and further in view of the Handbook of Cosmetic Science and Technology. These references, whether taken alone or in combination, fail to cure the defects of Totten et al. '145, Jacobs et al. '185, and Sang et al. '310. The claim rejections based thereon should accordingly be withdrawn.

Claims 15 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085. Claims 15 and 21 have been cancelled, thereby rendering moot the claim rejections thereof.

Claim 31 Stands rejected under 35 U.S.C §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085, and further in view of Sang et al. '310. Claim 31 has been cancelled in the present amendment, thereby rendering moot the claim rejection thereof.

Claim 22 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085, and further in view of Dener et al. '537 and Haider . Claim 22 has been cancelled, thereby rendering moot the claim rejection thereof.

For the foregoing reasons, the claims as now presented are believed to be unobvious and patentable over the cited prior art, whether taken alone or in combination. Applicant therefore submits that the claims as currently presented are allowable on the merits. An early allowance is respectfully solicited.

Respectfully submitted,

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